UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. ACCORD HEALTHCARE, INC., USA 1:13-cv-00335-TWP-DKL; APOTEX INC. 1:12-cv-499-TWP-DKL; and APOTEX CORP. 1:12-cv-499-TWP-DKL, Consol Defendants.	)	Case No. 1:12-cv-00086-TWP-MPB

ORDER ON MOTION FOR ENTRY OF JUDGMENT

This matter is before the Court on a Motion for Entry of Judgment filed by Plaintiff Eli Lilly and Company ("Lilly"). (Filing No. 89.) For the following reasons, the Court **grants** Lilly's Motion.

I. BACKGROUND

On August 10, 2010, U.S. Patent No. 7,772,209 ("Patent '209") was issued to Lilly. Patent '209 covers the method of administering ALIMTA®—an anti-cancer drug that requires physicians to co-administer the drug with folic acid and vitamin B_{12} to reduce the incidence of patient toxicity caused by ALIMTA®. This case arises out of the filing by Defendants Accord Healthcare, Inc. ("Accord"), Apotex Inc. and Apotex Corp. (collectively, "Apotex") of their Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of ALIMTA®. On January 20, 2012 and April 17, 2012, Lilly filed patent infringement complaints against Accord and Apotex,

respectively. Thereafter, on July 23, 2012, the Court granted Lilly's Motion to consolidate the cases against Accord and Apotex (collectively, "Defendants") (Filing No. 34).

Prior to filing complaints against Defendants, on October 29, 2010, Lilly filed a similar patent infringement action against Teva Parenteral Medicines Inc. ("Teva"), among other generic drug manufacturers. In light of the pending action against Teva and to conserve judicial resources, Lilly and Apotex, as well as Lilly and Accord, filed Joint Motions to Stay and Be Bound by the outcome of the Teva litigation. (Filing No. 73: Filing No. 76.) On October 7, 2013 and October 15, 2013, the Court granted the parties' motions. (Filing No. 75: Filing No. 77.)

Nearly two years later, on August 25, 2015, the Court entered final judgment in favor of Lilly and against Teva. *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 126 F. Supp. 3d 1037 (S.D. Ind. 2015), *aff'd*, 845 F.3d 1357 (Fed. Cir. 2017). The Court found the Teva "Defendants' ANDA Products indirectly infringe the Asserted Claims of [Patent '209]." *Id.* at 1043. The Court then entered final judgment:

> Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the pemetrexed product that is the subject of ANDA Nos. 90-352, 90-674, 90-384, and 91-111 SHALL NOT BE a date earlier than the latest date of expiration of Plaintiff, Eli Lilly and Company's United States Patent No. 7,772,209.

Case No. 1:10-cv-1373-TWP-DKL, ECF 420. On January 12, 2017, the United States Court of Appeals for the Federal Circuit entered judgment affirming this Court's decision. *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357 (Fed. Cir. 2017). The parties in *Teva* did not file a petition for writ of certiorari to the Supreme Court of the United States.

Thereafter, the Court granted joint motions for entry of final judgment against other ANDA filers who Lilly entered into parallel Stay and Be Bound Agreements, including Accord. (Filing No. 87.) The final judgment against Accord mimicked the language of the *Teva* final judgment.

See id. Apotex declined to agree to a similar final judgment and, on May 5, 2017, Lilly filed a Motion for Entry of Judgment against Apotex, in accordance with *Teva*. (Filing No. 89.)

II. DISCUSSION

In response to Lilly's motion, Apotex argues the Court should deny entry of final judgment, asserting because Lilly's request is premature. In the alternative, Apotex asks the Court to enter its proposed form of final judgment, rather than Lilly's.

A. Lilly's Motion for Entry of Final Judgment is not premature.

In their joint request to stay litigation and be bound by *Teva*, Lilly and Apotex agreed:

> Following the conclusion of all appeals (and any proceedings on remand and appeals therefrom), final judgment will be entered in the Apotex Action *in accordance with the Final Judgment of the Teva*/APP Litigation. That is, if Final Judgment, after all appeals, is entered in Lilly's favor in the Teva/APP Litigation, then final judgment shall be entered for Lilly and against Apotex in the Apotex Action.

(Filing No. 73 at 3) (emphasis added). The Court ordered: "[w]ithin 60 days following the final disposition of the Teva/APP Litigation, the parties…confer, prepare, and file jointly a proposed final judgment order, or, if appropriate, a status report, in conformance with the agreements set forth in their Joint Motion." (Filing No. 75.)

Apotex argues that Lilly's Motion for Entry of Judgment is premature because, at the time Lilly filed its request, the sixty-day allowance to file a proposed joint motion for final judgment had not expired. In reply, Lilly contends that the sixty-day deadline anticipated the parties would confer and jointly agree about the terms of the proposed final judgment; however, it became apparent during its meeting with Apotex that the parties would not agree on a joint form of judgment. The Court **denies as moot** Apotex's argument because the sixty-day deadline to meet, confer and propose a joint motion for entry of judgment expired June 12, 2017—well before the date of this Entry. Accordingly, entry of final judgment in favor of Lilly is not premature.

Apotex also asks the Court to delay entry of final judgment because, during the pendency of the *Teva* appeal, Apotex filed petitions to the Patent Trial and Appeal Board ("PTAB") seeking *inter partes* review ("IPR") of Patent '209. Apotex contends that PTAB granted the petition, and found "there is a reasonable likelihood that [Apotex] would prevail in demonstrating unpatentability of claims 1-22" of Patent '209. (Filing No. 90 at 5.) Apotex also filed a motion to join other IPRs initiated by Neptune Generics, LLC and Sandoz Inc. involving Patent '209. These petitions were granted and the PTAB's statutory deadline to issue a final decision on Patent '209's validity was mid-June 2017. *Id.* at 4-5. Apotex argues, because the PTAB may find Patent '209 invalid due to the lower evidentiary standard, final judgment is premature.

The Court again **denies as moot** Apotex's request because PTAB's deadline to enter a written decision expired. There is no evidence before the Court that Patent '209 is invalid. Additionally, even if the PTAB ruled that Patent '209 was invalid, the IPR proceedings have no bearing on the outcome of this dispute. Apotex and Lilly entered into an agreement that "if Final Judgment, after all appeals, is entered in Lilly's favor in the Teva [] Litigation, then final judgment shall be entered for Lilly and against Apotex...." (Filing No. 73 at 3.) This Court found Patent '209 valid and, similar to Teva, Apotex infringed upon the patent. Accordingly, because the Court of Appeals affirmed the Court's ruling regarding the validity of Patent '209 and the parties in *Teva* did not seek writ of certiorari with the United States Supreme Court, Lilly is entitled to entry of final judgment.

B. The Court declines to enter Apotex's proposed final judgment form.

In the alternative, Apotex asks the Court to enter its proposed form of final judgment, rather than an entry of judgment similar to those against Teva and Accord. Apotex essentially seeks to

include two additional provisions concerning: 1) the approval date of Apotex's product; and 2) the status of Apotex's paragraph IV certification.

1. Approval Date

Lilly asks the Court to order to enter final judgment stating:

> [p]ursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of any product that is the subject of ANDA No. 203774 shall be not earlier than the latest date of expiration of [Patent '209], including any period of pediatric exclusivity.

(Filing No. 89-1). On the other hand, unlike Lilly's proposed final judgment, Apotex requests the effective approval date to be the earlier of:

> a. the expiration of [Patent '209], including any period of pediatric exclusivity;
> b. the issuance of a mandate by the U.S. Court of Appeals for the Federal Circuit ruling that all the asserted claims of [Patent '209] are invalid in any appeal from a decision of the U.S. Patent and Trademark Office concerning the validity of the asserted claims of [Patent '209];
> c. the issuance of a mandate by the U.S. Court of Appeals for the Federal Circuit ruling that all the asserted claims of [Patent '209] are invalid in any appeal from a decision of a district court concerning the validity of the asserted claims of [Patent '209];
> d. in the event that the asserted claims of [Patent '209] patent are invalidated in a final written decision in the United States Patent and Trademark Office and no appeal has been filed, the expiration of the deadline to appeal; or
> e. in the event that the asserted claims of [Patent '209] are invalidated in a district court decision and no appeal has been filed, the expiration of the deadline to appeal.

(Filing No. 90-1). Lilly contends that this provision must be rejected because it is not in accordance with the holding in *Teva*. The Court agrees.

Apotex's provision differs materially from the *Teva* judgment because it enables Apotex to seek approval sooner than the expiration of Patent '209. In *Teva*, the Court found—and the Court of Appeals affirmed—that Patent '209 is valid. The Court barred defendants from launching their generic products before the expiration of Patent '209 because defendants would induce infringement of Patent '209. *See Teva*, 126 F. Supp. 3d 1037; *Teva*, 845 F.3d 1357. Accordingly,

because Apotex agreed to be bound by the holding in *Teva*, the Court **denies** Apotex's request with respect to this provision.

2. Apotex's Paragraph IV Certification

Apotex also proposes that the final judgment states:

> *Apotex is permitted to maintain its current paragraph IV certification* pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to [Patent '209] pending the exhaustion of all possible appeals of any actions concerning the validity of [Patent '209] before the United States Patent and Trademark Office (including inter partes review proceedings IPR2016-01429, IPR2016- 00318 IPR2016-00237, IPR2016-00240, IPR2016-01190 and IPR2016-01191) or before any district court, and any recertification to [Patent '209] shall not give rise to any statutory stays or delay in Apotex's approval.

(Filing No. 90-1) (emphasis added). In reply, Lilly argues that this proposed provision contravenes FDA regulations. *See* 21 C.F.R. § 314.94.

> *After finding of infringement. An applicant who has submitted a paragraph IV certification and is sued for patent infringement must submit an amendment to change its certification if a court enters a final decision from which no appeal has been or can be taken....* In its amendment, the applicant must certify under paragraph (a)(12)(i)(A)(3) of this section that the patent will expire on a specific date or, with respect to a patent claiming a method of use, the applicant may instead provide a statement under paragraph (a)(12)(iii) of this section if the applicant amends its ANDA such that the applicant is no longer seeking approval for a method of use claimed by the patent. *Once an amendment for the change has been submitted, the ANDA will no longer be considered to contain a paragraph IV certification to the patent*….

Id. (emphasis added).

The Court previously found Patent '209 valid and entry of judgment against Apotex proper. Accordingly, because federal regulations require Apotex to amend its certification—which results in a loss of paragraph IV certification to Patent '209—the Court **denies** Apotex's request on this issue. *See id.* ("Once an amendment…has been submitted, the ANDA will no longer be considered to contain a paragraph IV certification to the patent.")

III. CONCLUSION

For the reasons mentioned above, the Court **GRANTS** Lilly's Motion for Entry of Judgment. (Filing No. 89.) The Court specifically concludes that Lilly's request for entry of judgment is not premature and rejects Apotex's proposed final judgment order because it is not *in accordance with* the judgment in *Teva*. An entry of final judgment in accordance with Lilly's proposed text will follow in a separate order.

SO ORDERED.

Date: 8/11/2017

TANYA WALTON PRATT, JUDGE
United States District Court
Southern District of Indiana

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